Laser Machining, Inc.

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July 20, 1993

Dockets Management Branch (HFA-305)
Food and Drug Administration, RM 1-23
12420 Parklawn Drive
Rockville, MD 20857

Dear Sir or Madam:

RE: Intent to amend laser performance standard, docket no. 93 N-0044

The suggested amendments discussed in the May 10, 1993, Federal Register will be a welcome revision to the CDRH requirements. They should compliment the recent changes to the IEC 825 document and move toward achieving the goal of a world-wide set of common laser safety requirements. The commitment of the CDRH to harmonization of standards and the dedication of those involved in this effort is greatly appreciated.

There are a few items which I would like to see clarified, The following comments are provided and will match the item numbers in the notice of intent:

2. Suggest clarification of the last sentence of the first paragraph as follows: "However, for products for which long-term viewing or exposure is"... (to differentiate between products in which viewing or exposure would only occur fur short periods).

I assumed that products which emit in the near - IR range and which are, in effect, classified on the basis of 100s would continue to be so classified, even if they are general purpose products.

4. This change should be made only if the change to reduce the time period for classification in item 2 is also made. If this change is made without reducing the time period for classification, the result would be a lowering of the allowance power for some products and an inconsistency with the IEC 825 standard.

I would suggest that the first sentence be revised to read ".. .AEL of Class I for products with scanning or repetitively pulsed outputs. " (To clarify that this would apply also to scanning products.)

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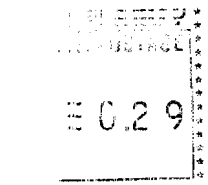

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